IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUST LITIGATION	**MDL 2724** **16-MD-2724**
	HON. CYNTHIA M. RUFE
THIS DOCUMENT RELATES TO:	
END-PAYER PLAINTIFFS' OVERARCHING CONSPIRACY CLASS ACTION COMPLAINT	**18-CV-2401**
INDIRECT RESELLER PLAINTIFFS' AMENDED OVERARCHING CONSPIRACY COMPLAINT	**18-CV-2533**
THE KROGER CO. ET AL. AMENDED COMPLAINT	**18-CV-284**
HUMANA, INC. AMENDED COMPLAINT	**18-CV-3299**

DEFENDANT WEST-WARD PHARMACEUTICALS CORP.'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF ITS MOTION TO DISMISS THE OVERARCHING CONSPIRACY CLAIMS FILED BY END-PAYER PLAINTIFFS, INDIRECT RESELLER PLAINTIFFS, KROGER PLAINTIFFS, AND HUMANA, INC.

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I. INTRODUCTION

Plaintiffs' Opposition[1] confirms that their claims against West-Ward are fatally flawed. It does not answer to the dispositive pleading deficiencies West-Ward identified in its motion. Plaintiffs do not even pretend that they alleged that *West-Ward* communicated with any other manufacturer about any other drug, or that *West-Ward* specifically knew about and purposely joined an overarching agreement concerning as many as 38 drugs *that it did not sell*.

Instead, Plaintiffs resort to wild speculation, relying entirely on, and asserting for the first time in Opposition, an un-plead hypothetical ANDA *theory* regarding West-Ward's purported *inaction*. Without any supporting factual allegations, Plaintiffs hypothesize that because West-Ward held a long-discontinued Abbreviated New Drug Application ("ANDA") for Meprobamate and an ANDA for Zoledronic Acid, its purported choice *not to immediately enter* those markets when prices rose must have been part of an overarching conspiracy that included a *quid pro quo* agreement from other manufacturers (not those that made Meprobamate or Zoledronic Acid) to stay out of the Doxycycline Regular Release ("Doxy RR") market. Yet no Complaint pleads any factual basis for these conclusions. No Complaint alleges that West-Ward communicated with any other manufacturer about Meprobamate or Zoledronic Acid, or that West-Ward was aware of any conduct in those markets. No Complaint alleges that *any* manufacturer refrained from entering, let alone agreed not to enter, the Doxy RR market. Further, Plaintiffs' ANDA theory ignores the many obvious reasons a manufacturer may not enter a specific drug market or re-commercialize a discontinued product.

In their 15-page Opposition, Plaintiffs do not, and indeed cannot, identify any factual allegations that permit an inference that West-Ward knowingly committed to the alleged

[1] As used herein, "Plaintiffs" collectively refers to End-Payer Plaintiffs ("EPPs"), Indirect Reseller Plaintiffs ("IRPs"), Kroger, and Humana.

common goal to raise prices and allocate customers for as many as 38 generic drugs it did not sell. This is not surprising. Plaintiffs base their claims on the States' Heritage-centric Complaint, which does not name West-Ward or include any drug West-Ward allegedly sold. Likewise, neither West-Ward nor the drugs Plaintiffs allege West-Ward sold (Doxy RR and Digoxin) are anywhere to be found in the 1,661-paragraph, 100-plus drug Complaint recently filed by the Plaintiff States. Here, unlike the Plaintiff States, Plaintiffs include West-Ward in their overarching conspiracy claims to cast as wide of a net as possible. But their pleading against West-Ward amounts to precisely the type of "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements" about which the Supreme Court has warned. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Plaintiffs choose conjecture over allegations of fact, and that is insufficient to raise a "plausible suggestion" that West-Ward committed to any purported conspiracy involving multiple drugs. *Twombly* and its progeny require dismissing Plaintiffs' overarching conspiracy claims against West-Ward.

II. ARGUMENT

A. Plaintiffs' Speculation About West-Ward's Purported Non-Entry Into the Zoledronic Acid and Meprobamate Markets Is Insufficient to Render Plausible West-Ward's Participation in an Overarching Conspiracy

Plaintiffs seek to subject West-Ward to joint and several liability for fixing prices for as many as 40 drugs not because of West-Ward's *actions*, but because of its supposed *inaction*. Plaintiffs' conjecture-laden ANDA hypothetical is the apex of what the Third Circuit terms the "loaded question fallacy," which bars a plaintiff from assuming a conspiracy and then setting out to prove it. *Valspar Corp. v. E.I. du Point de Nemours & Co.*, 873 F.3d 185, 198 (3d Cir. 2017). Here, Plaintiffs do exactly that; they start with the conclusion that West-Ward participated in an overarching conspiracy, and then work backward to support that conclusion by theorizing that West-Ward's *inaction* regarding Meprobamate and Zoledronic Acid proves its participation.

Rank speculation regarding West-Ward's inaction does not render plausible that West-Ward actively, knowingly, and intentionally joined a multi-drug conspiracy. To be clear, Plaintiffs do not plead in any way that West-Ward agreed not to enter the Meprobamate or Zoledronic Acid markets or that West-Ward even communicated with any Defendants selling Meprobamate or Zoledronic Acid.

Plaintiffs' inaction theory is woefully insufficient. Indeed, if the mere fact that West-Ward did not market two drugs is sufficient to plead its knowing and intentional participation in an overarching conspiracy involving up to 38 drugs it did not sell, then *every* generic drug manufacturer must attempt (and indeed would have a duty) to enter *each and every generic drug market* where existing sellers raise their prices regardless of the myriad reasons a manufacturer may choose not to market a particular drug at a particular time or whether they even have an active ANDA. If a manufacturer has a discontinued ANDA, like West-Ward had for Meprobamate, under Plaintiffs' logic it *must* take steps to reactivate the ANDA with the FDA; it *must* redevelop its supply chain and obtain the necessary ingredients regardless of its ability to obtain them in sufficient quantity and at a commercially reasonable price; it *must* devote financial resources to purchasing equipment without regard to whether that equipment makes sense in its larger production scheme; it *must* allocate manufacturing capacity regardless of the demand for and profitability of other drugs competing for limited space; and it *must* redevelop contracts and relationships with distributors to re-launch the drug without regard to company-wide objectives or strategy, all the while hoping that there are no regulatory difficulties and that there exists a market for the product by the time it is able to re-launch.[2] And even if a

[2] EPPs' Complaint and Plaintiffs' Opposition to West-Ward's motion include nothing about what it means to have a "discontinued" ANDA; instead they both include a footnote suggesting that "Discontinued ANDAs 'can be re-activated with relative ease.'" (EPP Compl. ¶ 115 n.52; Pls. WW Opp. at 4 n.6.). In support, EPPs' Complaint cites only a blog post discussing the *regulatory* process to return an ANDA to active status. EPPs completely ignore the

manufacturer doesn't have an ANDA for the drug, under Plaintiffs' theory it *must* nonetheless attempt to purchase or license an ANDA from an entity that does. Otherwise, the manufacturer must defend protracted litigation because, according to Plaintiffs, it *must* be plausible that the manufacturer purposefully stayed away from the market as part of a multi-drug price-fixing cartel. Plaintiffs' position ignores the many obvious alternative explanations for a manufacturer's non-entry into a drug market, and Plaintiffs' dependence on this speculative theory rather than on factual allegations from which one may plausibly infer agreement, speaks volumes.

Regardless of wholesale lack of merit of Plaintiffs' theory, there is an additional independent reason for dismissal. Although the foregoing arguments demonstrate why Plaintiffs' *theory* of "strategic inaction" is insufficient to plead West-Ward's plausible participation in an overarching conspiracy, Plaintiffs have not even *alleged* such a theory. Indeed, no Plaintiff actually pleads that West-Ward refrained from entering either the Zoledronic Acid or the Meprobamate market as part of any purported overarching conspiracy. None of the Complaints filed by IRPs, Kroger, or Humana contains *any allegation* that West-Ward held an ANDA, discontinued or otherwise, for Zoledronic Acid or Meprobamate, let alone that West-Ward took or refrained from taking any action related to those drugs or that it did so as part of a larger conspiracy reaching as many as 40 drugs. In their attempt to salvage their insufficient pleading against West-Ward through resort to this un-plead ANDA theory, IRPs, Kroger, and Humana misrepresent their Complaints to the Court. Humana, for example, does not even

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actual and significant operational steps a company would need to take before resuming manufacture of a drug (securing active ingredient supply, acquiring or re-purposing manufacturing equipment, completing quality testing), especially one that it has not made for several years. No discovery is needed to see that obvious point.

include Zoledronic Acid and Meprobamate in its list of drugs subject to the conspiracy; it does not plead anything about Zoledronic Acid at all. (*See* Humana Compl. ¶¶ 19-39.)

EPPs' Complaint fares no better. It contains no allegation regarding West-Ward's purported inaction in the Zoledronic Acid and Meprobamate markets. Indeed, Plaintiffs' Opposition to West-Ward's motion relies on just two paragraphs from EPPs' Complaint as "support" for their baseless ANDA theory, and neither addresses West-Ward's conduct. (Pls. WW Opp. at 5-7.) One consists entirely of a chart purporting to show the various ANDAs held by each Defendant. (EPP Compl. ¶ 115.) The other states that "[i]n 2013, Actavis exited the Meprobamate market, which left Heritage and Dr. Reddy's as the two remaining suppliers in the market. Heritage wanted to use Actavis' exit from the market as pretext to increase prices." (*Id.* ¶ 396.) This paragraph does not even mention West-Ward. Instead, it sets up Plaintiffs' other Meprobamate allegations, which claim that Dr. Reddy's and Heritage coordinated Meprobamate prices through direct communications. No Complaint suggests in any away that such coordination involved or depended on West-Ward. (*See id.* ¶¶ 394-414 (no reference to West-Ward); IRP Compl. ¶¶ 158-69 (same); Kroger Compl. ¶¶ 647-54 (same).) Plaintiffs' Zoledronic Acid allegations also do not mention West-Ward at all. (*See* EPP Compl. ¶¶ 369-93; IRP Compl. ¶¶ 146-57; Kroger Compl. ¶¶ 778-85.)

Moreover, Plaintiffs do not allege the counterpart to their ANDA theory—that West-Ward's purported "inaction" came in exchange for an agreement by any other Defendant to stay out of the Doxy RR, Digoxin, and/or any other drug market in which West-Ward participated. EPPs—again the only Plaintiffs to actually plead anything about ANDAs—do not allege that Heritage and Dr. Reddy's, the only two alleged Meprobamate conspirators, held ANDAs for

Doxy RR (or Digoxin). And no Complaint alleges that *any Defendant* agreed to stay out of the Doxy RR (or Digoxin) market as part of a multi-drug conspiracy.

Instead, unconcerned with making arguments without a foundation in the pleadings, Plaintiffs suggest for the first time in their Opposition that *West-Ward's* participation in the alleged overarching conspiracy may be inferred from the *non-entry* into the Doxy RR market of *Citron* and *Teva*, two manufacturers that did not sell Meprobamate or Zoledronic Acid. (Pls. WW Opp. at 5-6.) Aside from not being pled, this makes no sense and falls apart on many levels. First, EPPs concede Teva's Doxy RR ANDA was discontinued. (EPP Compl. ¶ 115.) Plaintiffs also concede Citron did not own a Doxy RR ANDA. (*See id.* ¶ 114.) Rather, Citron appears to have reached an agreement no later than July 2015 with Chartwell Therapeutics Licensing, LLC, the ANDA holder, to "market and resell [Doxy RR] to third-party retailers." *Chartwell Therapeutics Licensing LLC v. Citron Pharma LLC*, No. 16-cv-3181, 2018 U.S. Dist. LEXIS 36672, at *2 (E.D.N.Y. Mar. 4, 2018). In other words, Citron apparently did exactly what Plaintiffs say it should have done. Second, EPPs' and IRPs' standalone Doxy RR Complaints contradict their Plaintiffs' theory about entry into the Doxy RR market. They do not allege the Doxy RR conspiracy depended on the "strategic inaction" of any drug manufacturer. To the contrary, these Complaints allege that the characteristics of the Doxy RR market alone, including high barriers to entry, made it possible for the Doxy RR sellers to collude. (*See* WW Mem. at 9.) Third, Plaintiffs' Opposition concedes that "West-Ward did not hold an ANDA for any Drug at Issue sold by Citron" and so it could not "retaliate" if Citron entered the Doxy RR market. (Pls. Opp. at 6.) West-Ward similarly is not alleged to have sold or held an ANDA for any Drug at Issue sold by Teva. As such, there was no price competition for West-Ward to

"eschew" on another drug in exchange for either Citron's or Teva's purported agreement not to compete on Doxy RR. (*Cf.* EPP Compl. ¶ 103.)

Again, Plaintiffs modeled their overarching conspiracy claims on the Plaintiff States' Heritage-centric Complaint, which asserts claims for Meprobamate and Zoledronic Acid, but, tellingly, does not name West-Ward as a Defendant, does not include claims for Doxy RR or Digoxin, and does not allege that the success of any conspiracy regarding Meprobamate or Zoledronic Acid was dependent on West-Ward's inaction in either market. (*See* Plaintiff States Compl., Case No. 17-3768, ¶¶ 149-79.) No amount of creative speculation in Opposition can change the lack of factual allegations concerning West-Ward in these Plaintiffs' Complaints.

In short, Plaintiffs' ANDA theory is cut from whole cloth, not supported by allegations in any Complaint, and insufficient to create an inference that West-Ward plausibly knew of, and joined, any multi-drug conspiracy.

B. Plaintiffs' Oppositions Demonstrate That Their Overarching Conspiracy Allegations Do Not In Any Way Implicate West-Ward

Plaintiffs press their un-plead hypothetical ANDA theory in opposition to West-Ward's motion precisely because they cannot point to factual, non-conclusory allegations in their Complaints rendering it plausible that West-Ward joined an overarching multi-drug conspiracy. Plaintiffs' joint and individual Oppositions emphasize West-Ward's *exclusion* from the allegations fundamental to their claims. (*See* WW Mem. at 3, 6-7.)

For instance, in laying out the "ample factual material" purportedly establishing the plausibility of the overarching conspiracy, Plaintiffs' joint Opposition to Defendants' joint motion concedes that central to their claims are allegations that Defendants "*reach[ed] out* to whatever combination of competitors were manufacturing, or planned to manufacture, a particular drug and come to an agreement," and that Defendants supposedly "often discussed or

agreed to conspiratorial conduct across multiple drugs at the same time and *were in constant contact* with each other." (Pls. Opp. to Joint Mot. at 5 (emphasis added).) But no Complaint alleges West-Ward communicated *even once* with any other Defendant.

Plaintiffs' individual Opposition memoranda similarly exclude West-Ward in their attempts to explain the workings of the alleged overarching conspiracy. EPPs' individual Opposition makes only a handful of passing references to West-Ward, two of which acknowledge that the Plaintiff States did not include West-Ward or Doxy RR in their Heritage-centric Complaint, and none which tie West-Ward's conduct to any drug other than Doxy RR. (*See* EPP Opp. at 1, 19.) The three references to West-Ward in IRPs' individual Opposition likewise do not implicate West-Ward in a multi-drug agreement, and one acknowledges only that West-Ward has individually moved to dismiss IRPs' Complaint. Expectedly, the Kroger and Humana Oppositions do not reference West-Ward even once; each of their Complaints excludes West-Ward from their group of alleged "Core Conspirators" and contains no factual allegation connecting West-Ward to any multi-drug agreement. (*See* WW Mem. at 11-14.)

Plaintiffs do not rebut "West-Ward's litany of things that 'no complaint alleges' concerning its communications or its actions." (Pls. WW Opp. at 13.) Instead, Plaintiffs rely on the factors in *United States v. Kelly* to excuse the lack of specific pleading as to West-Ward. 892 F.2d 255 (3d Cir. 1989). Although Plaintiffs claim they "'need not prove that each defendant knew all the details, goals, or other participants' in order to find a single conspiracy" (Pls. WW Opp. at 13 (quoting *Kelly*), they certainly do need to allege with specificity that West-Ward knew of, and committed to, a common goal that went beyond its alleged pricing conduct in the individual Doxy RR market (or Digoxin market in in the case of Kroger and Humana) and that the individual conspiracies joined by individual Defendants were interdependent. *Kelly*, 892

F.2d at 258-60. For the reasons stated above, Plaintiffs' un-plead ANDA theory cannot satisfy this requirement.

With respect to the third *Kelly* factor, which concerns "overlap" among the individual alleged conspiracies, Plaintiffs point only to the mere fact of West-Ward's attendance at trade association events, a general activity of generic pharmaceutical companies (as well as customers, government agencies, industry consultants, etc.). No Complaint specifically alleges that West-Ward actually participated in any illicit conduct at any such event. (Pls. WW Opp. at 10-11.) And Plaintiffs' claim that West-Ward's mere trade association attendance sufficiently establishes the *Kelly* "overlap" factor is inconsistent with the law. *Kelly*, like other cases, requires that the same entities or individuals were involved in the multiple individual conspiracies; it is not enough that alleged conspirators may have interacted in everyday business settings (like trade association events). *See, e.g.*, *United States v. Kemp*, 500 F.3d 257, 291 (3d Cir. 2007). EPPs and IRPs allege that West-Ward only participated in one of the alleged sub-conspiracies, for Doxy RR, and cannot plead *West-Ward* into a broader multi-drug conspiracy through allegations that *other* Doxy RR manufacturers may have been conspiring as to *other* drugs. *In re K-Dur Antitrust Litig.*, No. 01-cv-1652, 2016 U.S. Dist. LEXIS 22982, at *87-89 (D.N.J. Feb. 25, 2016) (the presence of a "common party" is insufficient to establish overlap; the accused conspirator must have "knowingly cooperated in the common effort"). Similarly, Kroger's and Humana's theory that they can establish overlap through allegations that "a small group of Core Conspirators participated in all the individual drug conspiracies" (Kroger Opp. at 15) has been flatly rejected by the Third Circuit. *See Kemp*, 500 F.3d at 291 (finding insufficient the assertion that "the core conspirators . . . dealt with every one of the coconspirators").

Plaintiffs general recitation of the *Kelly* factors is not a surrogate for allegations of fact rendering it plausible that West-Ward knew of and purposefully joined a conspiracy that involved as many as 40 drugs. Plaintiffs' Opposition memoranda underscore that those allegations are absent here, further demonstrating that West-Ward's motion should be granted.

III. CONCLUSION

For the reasons stated above and in its opening brief, West-Ward again respectfully requests that this Court grant its motion and dismiss with prejudice all claims against West-Ward in the EPP and IRP Complaints and the overarching conspiracy and Doxycycline claims against West-Ward in the Humana and Kroger Complaints.

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Respectfully submitted,

/s/ Jan P. Levine

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CERTIFICATE OF SERVICE

I hereby certify on this 13th day of June 2019, a true and correct copy of the foregoing was filed electronically and is available for viewing and downloading from the Court's ECF System. Notice of this filing will be sent to all counsel of record by operation of the ECF System.

Dated: June 13, 2019

/s/ Jan P. Levine
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